SEP 19 2008

K081779

TAB 5

510(K) SUMMARY

Date of Submission	June 20, 2008
Official Contact	Zita A. Yurko Director Regulatory Affairs Respironics, Inc. 1740 Golden Mile Highway Monroeville, PA 15146 zita.yurko@respironics.com 724-387-4120 t 724-882-4120 c 724-387-7490f
Classification Reference	21 CFR 868.5655
Product Code	BYJ – Portable Liquid Oxygen Unit
Common/Usual Name	Portable Liquid Oxygen Unit
Proprietary Name	Respironics GoLox-93
Predicate Device(s)	Respironics GoLox USP (K072723) Caire Spirit Model HAS (K050153)
Reason for submission	device modification

Substantial Equivalence

The GoLox-93 has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

The GoLox-93 is a modification to the GoLox USP (K072723) to enable it to be filled with 93% liquid oxygen from the Respironics Home Liquefactions Systems. The GoLox- 93 is identical to the GoLox USP except for the fill connection. The fill connector has changed to allow filling with 93% oxygen from liquefaction systems only and prevents filling with USP oxygen from stationary vessels.

The GoLox USP (K072723) was a modification of the Respironics PLOX (K050414). Comprehensive testing was performed to determine equivalence between the GoLox USP (K072723 and PLOX (K050414). Additional testing provided includes verification that the fill connector mates with liquefaction systems and not with stationary vessels.

Intended Use

The GoLox-93 is intended to provide supplemental oxygen to patients who have difficulty extracting oxygen from the air that they breathe. The patients would normally receive oxygen via a nasal cannula. It is intended for ambulatory use inside and outside of the home. It is not intended to be life supporting or life sustaining. The device has no contraindications.

Device Description

The GoLox-93 is a double walled vacuum insulated cryogenic vessel designed to hold approximately 1 pound of liquid oxygen at a pressure of 22 psig with heat exchange tubing, relief valves and a pneumatic conserving device housed in a plastic enclosure. Oxygen is stored under low pressure in its liquid state where the pressure is limited by the pressure relief valve. The liquid oxygen is converted to near ambient temperature gaseous oxygen through a system of tubes and warming coils for delivery to patients requiring supplemental oxygen by a single lumen cannula. The device is not intended as life support or life sustaining. The GoLox-93 is a mechanical device and does not contain any electronics or software. The GoLox-93 is designed to be refilled only from Respironics Home Liquefaction Systems.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2008

Ms. Zita A. Yurko
Director, Regulatory Affairs
Respironics, Incorporated
Sleep & Home Respiratory Group
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K081779
Trade/Device Name: GoLox-93
Regulation Number: 21 CFR 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: June 20, 2008
Received: June 23, 2008

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): _____

Device Name: GoLox-93

The GoLox -93 is intended to provide supplemental oxygen to patients who have difficulty extracting oxygen from the air that they breathe. The patients would normally receive oxygen via a nasal cannula. It is intended for ambulatory use inside and outside of the home. It is not intended to be life supporting or life sustaining. The device has no contraindications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081779